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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,235	10/29/2001	Barbara S. Fox	110001.123	9886

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HALE AND DORR, LLP
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EXAMINER
WALLS, DIONNE A

ART UNIT	PAPER NUMBER
1731	5

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,235	FOX, BARBARA S.	
	Examiner	Art Unit	
	Dionne A. Walls	1731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 April 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3-4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

1. This application makes a claim for domestic priority under 35 USC 119(e); however it lacks the necessary reference to the prior application. A statement reading "This Application claims the benefit of US. Provisional Application No. 60/245,490, filed on November 3rd, 2000." should be entered following the title of the invention or as the first sentence of the specification.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/285016. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are anticipated by the claims of 10/285,016 since the instant claims are broader and more generic than those of 10/285,016.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 20, 22-23, and 36 rejected under 35 U.S.C. 102(b) as being anticipated by Slutsky et al (US. Pat. No. 6,102,036) .

Slutsky discloses all that is recited in the claims (see cols. 10-12 and figs. 3A – 3C).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-9, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al (US. Pat. No. 6,106,845) in view of Ruecroft et al (US. Pat. No. 5,663,356).

Wong et al discloses all that is recited in the claims (see cols 3-8 and figs. 1A-3B) except it may not state that the oral active agent is nicotine. However, Wong et al does state that the active agent can be one of any large number of substances which provide

some pharmacologic effect, such as drugs that act on the central nervous system. Further, Ruecroft et al discloses, in its "Background of Invention" section, that nicotine is known to have a number of pharmacological effects, and has been used in the treatment of neurological disorders (see col. 1, lines 39-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize nicotine as the active agent because of the benefits associated the substance in the treatment of certain diseases.

Regarding claims 2-3, based on the disclosure of a tube shape of the chamber of Wong et al, coupled with the disclosure that states that the device can be between about 10 – 30 cm in length, it follows that said chamber approximates the shape of both a conventional cigarette and a drinking straw, since both are merely slender cylindrical objects and the typical length of both cigarettes or straws would lie somewhere within this range.

Regarding claims 6-8, while Wong et al modified by Ruecroft et al may state that the active agent may be coated nicotine particles, it may not specifically mention the claimed coating materials. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize any one of the listed substances (i.e. sugar) to provide a film of coating material on the particulate since these materials are well-known in many arts for serving this purpose.

Regarding claims 9, and 14-15, Wong et al modified by Ruecroft et al teaches that, preferably, the amount of active agent to be delivered to the user (i.e. the amount contained in the tubular chamber) is between 25-5000 mg (corresponding to the

claimed "4-144 mg"). While the combined references may not specifically teach that the tubular chamber contains 4-12 mg of nicotine, Wong et al does teach that the amount of active agent will vary depending on the particular agent, the severity of the condition and the desired therapeutic effect (see col. 7, lines 43-48). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver the nicotine agent in the claimed amount, after routine experimentation to determine the optimal amount needed to achieve the desired result.

8. Claims 10-12, 16-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al (US. Pat. No. 6,106,845) in view of Ruecroft et al (US. Pat. No. 5,663,356), further in view of Westman et al (US. Pat. No. 6,211,194).

These claims differ from Wong et al modified by Ruecroft et al because of language that recites that a solution of nicotine (as a suspension) is formed when the liquid enters the chamber and contacts the nicotine, said nicotine being selected from the group consisting of levo nicotine, dextro nicotine, racemic mixtures thereof, and pharmaceutically acceptable salts thereof, and said solution having acidic pH and including a flavoring. However, Wong et al does disclose that the active agents can be delivered in various forms, such as soluble or insoluble molecules (see col. 7, lines 39-40). This would have suggested to one having ordinary skill in the art that said active agent molecules can be combined, with the liquid, to form a solution of suspended nicotine particles. Further, Westman et al discloses a solution containing nicotine particles for treating various medical ailments, said nicotine employed in the solution being levo or dextro nicotine, or a racemic mixture of both; said nicotine solution having

a pH adjusted to be acidic, containing a flavoring and delivered to the user so as to result in blood levels of about 2-30 ng per 1 ml of blood (see cols. 5 and 6). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the nicotine solution in Westman et al into the device of Wong et al modified by Ruecroft et al since such solution, containing an active agent, is designed to treat various medical conditions – which is consistent with the teaching of Wong et al - and is provided as conveniently dispensed, palatably acceptable, well-tolerated formulations.

Regarding claim 22, while not explicitly stated, it follows that not only would liquid enter the tubular chamber when the solution is administered to the user, but air (corresponding to the claimed "gas") would also be delivered to the user, obviously provided from an external source (i.e. the atmosphere).

Conclusion

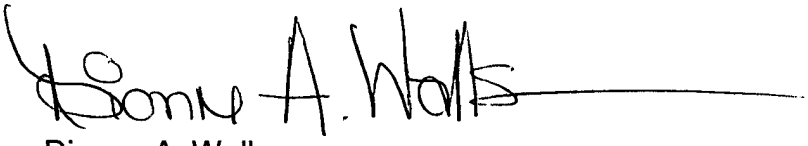
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dionne A. Walls whose telephone number is (703) 305-0933. The examiner can normally be reached on Mon-Fri, 7AM - 4:30PM (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven P. Griffin can be reached on (703) 308-1164. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.



Dionne A. Walls
May 3, 2003